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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,372	07/11/2003	Mark G. Gilreath	P-4438-US	2855
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Pearl Cohen Zedeck Latzer, LLP 1500 Broadway 12th Floor New York, NY 10036			EXAMINER	
			KISH, JAMES M	
		ART UNIT	PAPER NUMBER	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/617,372	<b>Applicant(s)</b> GILREATH ET AL.
	<b>Examiner</b> JAMES KISH	<b>Art Unit</b> 3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 10 November 2008.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-4,7-11 and 18-23 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-4,7-11 and 18-23 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/3/08

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

On the top of page 8, the Applicant argues a topic that was discussed in the Interview on November 3, 2008. This topic is that "more components may be considered to be 'behind' the window than what the Applicants claim are 'behind' the window." And that "the Examiner's suggested alternate positioning is not possible, as objects at a remote distance away from the optical window to the side thereof, even if situated behind the extended plane of the window, cannot reasonably be considered to be 'behind' the window. The Examiner respectfully disagrees. The claims are read in the broadest reasonable interpretation. As an example of a reasonably broad interpretation of the term "behind" one might consider the scenario in which a large group of people are making a decision to follow one leader of the group over the other leader. In this example, a line is drawn in the sand and people are asked to stand *behind* the line with which ever side they agree with. Even if someone were to walk five steps to the side from where the line ends and then cross the boundary created by the line, that person is considered to have crossed the line and therefore, stands "behind" (or in front of) the opposite side of the line.

Furthermore, the Examiner urges the Applicant to see paragraph 59 of US Patent Publication No. 2007/0232852 (having a common assignee) where the use of relative terms are described.

Regarding the Applicant's argument and amendment of "window" to "dome," the Examiner suggests that "a transparent dome" improves the language because as stated, the dome may have any optical property. This may include being absorbent of light, it may refract light like a prism, it may allow light to pass through unchanged, it may completely reflect light, etc.

### ***Claim Objections***

Claims 1-4, 7-11 and 18-23 are objected to because of the following informalities:

Claim 1 is objected to because the term "operate through" in line 8 is unclear. The image sensor and the lens do not perform any operation *through* the optical dome. Furthermore, the illumination source does not perform an operation *through* the optical dome – the light produced by the illumination source passes through. Operation generally implies that there is a change or effect based on the operant.

Claim 7 is objected to for being dependent from a cancelled base claim.

Claim 8 is objected to for being unclear. The claim reads, "comprising a transmitter." It is unclear how the tool comprises a transmitter, meaning, where it is incorporated structurally.

Claim 21 is objected to because the limitations provided are intended use and do not further limit the structure of the apparatus.

Claim 22 is objected to for failing to further limit the claim from which it depends. Claim 1 already states that a lens is behind the dome. Therefore, "an optical system" is already behind the dome.

Claim 23 is objected to for being unclear. The claim reads, "comprises a battery." It is unclear how the tool comprises a battery, meaning, where it is incorporated structurally - what is it connected to, if anything.

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 8, 11, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adair (US Patent No. 5,817,015) in view of Kubota (US Patent No. 4,319,563). Adair discloses an endoscope with a transparent window at the distal end

thereof (see Abstract). Figure 9 illustrates the window as covering all of the optical elements of an imaging portion of the endoscope. As seen here, there is a central body having an in-vivo and a non-inserted end. Adjacent the proximate end of the sheath is a plastic cover (column 5, lines 45-46). Numeral 70 illustrates two steering wires (i.e., guidewires), which allow an operator to perform in-vivo procedure, including steering the endoscope's tip. The wires are connected at the proximal, non-inserted end to a control 72 (column 6, lines 27-32). The imaging unit comprises an image sensor (see numeral 16 of Figure 3), a lens (see numeral 19 of Figure 2), a plurality of illumination source (see numeral 14 of Figures 2 and 3) all of which are placed behind an optical window (column 4, lines 28-49). A transmitting electronic means is connected to the image sensor circuit board (see Abstract). The device has multiple channels, as illustrated by, at least, numerals 14 in most figures. However, the optical window of Adair is not disclosed as being a dome. Kubota teaches an endoscope with a convex dome shaped optical window. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the dome shaped end of Kubota in the system of Adair because the dome shaped end reduces the possibility of damage to the living body (column 1, lines 30-36).

Claims 1-4, 7-10, 18-20 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. (US Patent No. 5,681,260) – herein referred to as Ueda - in view of Gazkzinski (US Patent Pub No. 2001/0051766). Ueda discloses a guiding apparatus for guiding an insertable body within an inspected object. As illustrated in

Figure 2, the insertable tip of the device comprises an imaging unit (see column 7, line 53 through column 8, line 12) and a functional unit is provided in several of the embodiments (see column 23, lines 33-34; it states, "... can be applied not only to an endoscope but also to a catheter."). As mentioned further in Claim 4, the functional element may encompass a catheter. As illustrated in Figure 1(a), a controlling apparatus is included in the Ueda device. In one embodiment, an LED is utilized as the illumination device powered by a battery (see column 18, lines 9-27 and Figure 27). Information and instruction can be sent wirelessly between the device and the controlling apparatus (column 18, lines 27-38). Also, sensors such as pH and temperature sensors may be provided (column 18, lines 52-60). Information can be passed to and from the device via a transmitter and a receiver (column 18, lines 18-20). Within the process circuit, there is a memory unit, as described in column 24, lines 35-47. However, Ueda does not disclose a device wherein the illumination source, an image sensor and a lens are behind a single optical dome. Gazdzinski teaches an improved endoscopic device. The imaging portion of the device comprises an optional lens cover that covers the lenses and seals an aperture. A plurality of other components (including, *inter alia*, a CCD or other imaging array, not shown) is disposed within the aforementioned cavity (paragraph 145 and Figure 3). Also shown in Figures 10a-b, the lens cover is placed over illumination sources, the imaging sensor and at least three lenses. The cover is dome shaped, thereby fitting with the generally cylindrical shape with rounded ends of the probe (paragraphs 174-175). It would have been obvious to one of ordinary skill in the art at the time the invention was made to

incorporate the design of the imaging portion of Gazdzinski in the system of Ueda to condense the imaging portion to reside entirely in the front portion of the device, thereby alleviating the need for the use of lumens to carry light to the tip and simplifying the device. Furthermore, by using rounded contours it will mitigate the possibility of laceration or "catching" on the intestinal epithelium. Gazdzinski discusses with regarding "scoops," however, the teaching is applicable to the distal end of an endoscopic device, such as the distal end of Ueda, which would also have reduced risk of "catching."

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda in view of Gazdzinski, as applied above to claims 1, and further in view of Ishikawa et al. (US Patent No. 6,264,611). The Ueda combination is described above. However, the wireless transmission is not explicitly described as being RF energy. Ishikawa discloses a ball-shaped monitoring device for use with an instrument that is insertable into a human body. One application of the ball sensor is to place it at the tip of a guidewire used in interventional procedures, such as balloon angioplasty (column 4, lines 45-65). Figure 3 shows a balloon catheter system that could utilize the ball sensor. The figure shows a guidewire 10 at the non-inserted end. The device may be made of silicon or metals (column 15, lines 16-30). The ball sensor provides information to a remote processing system via RF signals. See Figure 7. Column 18, lines 15-38 discuss various applications of the ball sensor, including use with ultrasound and other imaging catheters. It would have been obvious to one having ordinary skill in the art at the time

the invention was made to utilize RF energy as the means to provide a wireless connection as taught by Ishikawa as a well known method to those of skill in the art.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda in view of Gazdzinski, as applied above to claims 1, and further in view of Snone et al. (US Patent No. 5,846,221). The Ueda combinations are described above. However, Ueda does not state that the device is disposable. Snone teaches a steerable catheter having a disposable module and sterilizable handle. The module includes an imaging means to be positioned within the body of the handle for transmitting images from within the human body (column 18, lines 55-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a disposable insert portion because these small or narrow working channels or lumens are difficult to clean and sterilize (column 2, lines 15-17).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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